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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,262	04/02/2008	Ronald P. Lesser	61612(71699)	9788

49383 7590 04/01/2011

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EXAMINER	
SCHAETZLE, KENNEDY	
ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
04/01/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,262	LESSER ET AL.	
	Examiner	Art Unit	
	Kennedy J. Schaetzle	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-10,29-35,37,38,40 and 62-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-10,29-35,37,38,40 and 62-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 10, 32 and 40 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Eckerson (Pat. No. 4,865,048).

See the text abridging cols. 1 and 2, as well as col. 2, lines 60-69.

Regarding the newly added recitations concerning neck location as it pertains to method claim 1, Eckerson is considered to inherently apply electric current to a vagus nerve located in the neck (again, see col. 2, lines 60-69).

Specifically regarding method claim 32 (with the same comments applying to broader claims 1 and 40), since the mastoid process functions to anchor muscles of the neck, the skin overlying this anchor point and thus the neck muscles can be considered to constitute neck skin. In any event, Eckerson teaches to place the electrodes on the mastoid process in close proximity to the vagus nerve. Those of ordinary skill in the art looking to stimulate the vagus nerve would have found it obvious to at least try placing the electrodes of Eckerson on the skin of the neck in order to ensure that the vagus nerve is adequately stimulated since, as the applicants argue on page 5 of the Remarks, "...the mastoid process is not innervated by the vagus nerve...".

Regarding apparatus claim 40, the skin-contacting electrodes of Eckerson are clearly and on their face inherently capable of being placed at least on the skin of the neck if one so desires (see Fig. 1). Prior art apparatus does not need to be shown placed in the same location --it is sufficient to simply be capable of such placement.

Claim Rejections - 35 USC § 103

4. Claims 5-9 and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckerson.

Regarding claim 5, while Eckerson states that the electrodes are surface electrodes, it is old and well-known in the medical nerve stimulator arts to place electrodes either on the surface for non-invasive placement, or implanted within the body for chronic stimulation. The decision

is clearly application dependent. For instance, patients requiring only short-term treatment may prefer skin placement of the electrodes to avoid the unnecessary trauma of surgery, while those requiring chronic treatment may opt for implant of the electrodes to avoid unsightly wires and the inconvenience and potential embarrassment of wearing a contraption for long periods of time. Patients suffering from mental or physical disabilities might also benefit from an implanted system not requiring conscious action to properly place the apparatus and control the stimulus treatment times. In the previous Office Action, the examiner took Official Notice that the subject matter of claim 5 was old and well-known. Lacking any effective timely traversal of this notice, the feature is now considered admitted prior art.

Regarding claims 6-9, inductively controlled implantable devices are old and well-known in the medical arts. Such a system allows for non-invasive transmission of power and data to and/or from the implant without the need for invasive conductors which are prone to infection, and allows the implant to operate independently of any battery or implanted power source. Said systems also allow for the recharging of rechargeable batteries, thus negating the need to surgically remove the battery when the charge has been depleted. In the previous Office Action, the examiner took Official Notice that the subject matter of claims 6-9 was old and well-known. Lacking any effective timely traversal of this notice, the features are now considered admitted prior art.

Regarding claim 62, while Eckerson does not explicitly state that the stimulation is actuated manually, Eckerson does disclose that the patient may control the amount of time that the system is activated (see for example col. 2, lines 13-29, col. 3, lines 32-37, etc.). Common sense would indicate that if the patient has control over the therapy length, the patient would

need to have the ability to manually actuate and deactivate stimulation –especially over extended periods of treatment and at-home care where medical personnel may not be available when symptoms arise. Such a feature would have been considered obvious to those of ordinary skill in the art since it would allow the patient an effective measure of control over his/her treatment.

5. Claims 1, 2, 5, 6-9, 29, 30, 31, 33, 40 and 62-65 are rejected under 35 U.S.C. 103(a) as obvious over Marchal et al. (Pat. No. 6,853,862).

Regarding claim 1 and claims with similar limitations, Marchal et al. disclose a method for treating nausea and/or vomiting caused by pregnancy, motion sickness, or chemotherapy (see col. 6, lines 19-67), comprising the step of: applying electrical current from an external current source (see col. 4, lines 19-25, col. 5, lines 39-50, etc.) to a vagus nerve of a patient (see col. 3, lines 34-63) to reduce nausea and/or vomiting.

While Marchal et al. do not disclose applying electrical current to a vagus nerve located in the neck, stimulation of the vagus nerve in general is taught (see col. 3, lines 34-63). Marchal et al. teach that electrical stimulation of the vagus nerve with their invention is thought to cause impulses that can travel to the brain via vagal afferent pathways, and back to the pancreas via vagal efferent pathways (see col. 3, lines 45-63 and col. 5, lines 11-38 for example). Marchal et al. also state that the particular location for electrode placement is dependent upon a number of factors including extent of enervation and vagus nerve accessibility (see col. 5, lines 1-10), listing the stomach and intestine as examples of locations that are both well enervated and accessible. Given that the neck is also a location from a finite number of locations where the vagus nerve exists in substantial form and is easily accessible, and given the fact that impulses traveling along the vagus nerve to the brain through the neck are suitable to the Marchal et al.

invention, those of ordinary skill in the art would have seen the obviousness of at least trying to apply electrical current to a vagus nerve located in the neck with a reasonable expectation of success.

Regarding claims 6-9, 31, 33 and 65, inductively controlled implantable devices are old and well-known in the medical arts. Such a system allows for non-invasive transmission of power and data to and/or from the implant without the need for invasive conductors which are prone to infection, and allows the implant to operate independently of any battery or implanted power source. Said systems also allow for the recharging of rechargeable batteries, thus negating the need to surgically remove the battery when the charge has been depleted. In the previous Office Action, the examiner took Official Notice that the subject matter of claims 6-9, 31, 33 and 65 was old and well-known. Lacking any effective timely traversal of this notice, the features are now considered admitted prior art.

Regarding claims 29 and 30, Marchal et al. disclose that pregnant women with morning sickness who experience nausea and vomiting may benefit from vagus nerve stimulation (see for example col. 6, lines 25-38). It is considered inherent that if one is attempting to treat a pregnant woman suffering from nausea and/or vomiting, one must first select and/or identify the woman.

Regarding claim 62, note the text abridging cols. 5 and 6.

Regarding claim 63, note col. 6, lines 3-24.

Regarding claim 64, the examiner considers the preset pulse width to constitute a turning on and off of the stimulation at predetermined times (e.g., at a specific period and frequency).

6. Claims 10 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal et al. in view of Barrett et al. (Pat. No. 6,609,025).

Regarding claim 10 with similar comments applying to claim 32, while Marchal et al. disclose that the stimulator may reside outside the patient (col. 4, lines 19-25), they do not explicitly state that the electrodes are placed on the skin. Barrett et al., however, discloses that the vagus nerve may be stimulated directly (i.e., with an electrode cuff placed about the nerve), indirectly from an implanted position (i.e., with an electrode implanted remote from the vagus nerve), or indirectly and non-invasively (see col. 7, lines 54-67). By definition a non-invasively placed electrode must reside on the skin. Given the fact that those of ordinary skill in the art recognize that the vagus nerve may be effectively stimulated from a variety of electrode locations including both invasive and non-invasive locations, those of ordinary skill in the art would have considered the exact placement of the electrode to be one of obvious design with the condition and needs of the patient dictating the most appropriate site from which to base stimulation. As argued above, patients requiring only short-term treatment may prefer skin placement of the electrodes to avoid the unnecessary trauma of surgery, while those requiring chronic treatment may opt for implant of the electrodes to avoid unsightly wires and the inconvenience and potential embarrassment of wearing a contraption for long periods of time. Patients suffering from mental or physical disabilities might also benefit from an implanted system not requiring conscious action to properly place the apparatus and control the stimulus treatment times. As can be seen, a host of factors may influence electrode location, with careful consultation between the surgeon and individual patient dictating the most appropriate stimulation site.

7. Claims 34, 35, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchal et al. in view of Bertolucci (Pat. No. 4,981,146).

Marchal et al. do not explicitly discuss application of the method to chemotherapy patients or patients suffering from motion sickness. Common sense would indicate to one of ordinary skill in the art that any system capable of reducing nausea and/or vomiting for pregnant women would be useful to treat chemotherapy and motion sickness patients since these patients frequently suffer from nausea and vomiting as well. In the very least it would have been reasonable to try the method of Marchal et al. on such patients with a reasonable expectation for success since one would expect substantially similar symptoms to be treatable with substantially similar treatments.

In any event, Bertolucci discloses that chemotherapy patients and those suffering from motion sickness may benefit from nerve stimulation in the treatment of nausea and/or vomiting. To therefore apply the method of Marchal et al. to chemotherapy and motion sickness patients would have been considered obvious by those of ordinary skill in the art.

Response to Arguments

8. Applicant's arguments filed January 14, 2011 have been fully considered but they are not persuasive.

Regarding the rejection of claims 1, 2, 10, 32 and 40 under 35 U.S.C. §102(b) as being anticipated by Eckerson, the applicants argue that the addition of limitations regarding the cause of nausea and vomiting and the location of the electrodes is sufficient to distinguish over the Eckerson reference since the patent does not disclose treating nausea and vomiting caused by

pregnancy, motion sickness, or chemotherapy. The applicants further argue that Eckerson "…does not provide for stimulating the vagus nerve because the mastoid process is not innervated by the vagus nerve," (page 5 of the Remarks).

The intended field-of-use for an apparatus or method, or the location of structure with respect to the body in an apparatus claim, is not, however, alone sufficient to saliently distinguish over prior art inventions capable of similar placement and operation. The skin-contacting electrodes of Eckerson are clearly capable of being placed at least on the skin of the neck if one so desires (see Fig. 1). Furthermore, and contrary to the applicants' assertions, the method and apparatus of Eckerson is indeed designed to stimulate the vagus nerve (see col. 2, lines 65-68), and alleviate symptoms of nausea and vomiting (see col. 2, lines 3-12). Whether or not the mastoid process is innervated by the vagus nerve is immaterial since Eckerson explicitly states that the intent of the device is to stimulate the vagus nerve.

Lacking any evidence to the contrary, and in view of the explicit teachings of Eckerson to electrically stimulate the vagus nerve (which dictates that the vagus nerve in the neck must be stimulated since the applicants argue that the mastoid process is not innervated by the vagus nerve), those of ordinary skill in the art would consider the system of Eckerson to be substantially similar to that of the present invention and thus inherently capable of treating nausea and vomiting caused by pregnancy, motion sickness, or chemotherapy.

Regarding the rejection of claims 10 and 32 as being obvious over Marchal et al. in view of Barrett et al., the applicants argue that because Barrett et al. only teach indirectly stimulating the vagus nerve at a subdiaphragmatic location, there is no teaching to stimulate the vagus nerve in the patient's neck.

The Barrett et al. reference was not applied for its teaching of neck stimulation per se (as evidenced by the fact that this newly added limitation was not present in claims 10 and 32 when Barrett et al. was applied in the previous Office Action), but rather for its showing that many different ways of effectively stimulating the vagus nerve are known –including non-invasive techniques such as through the skin. It is unclear –and the applicants proffer no explanation—as to why indirect stimulation of the vagus nerve through a subdiaphragmatic location would teach away from applying electrodes on the skin at other locations. The reason for why it would have been obvious to at least attempt stimulation through the neck with the Marchal et al. invention has already been discussed above.

Regarding the applicants' assertion that Marchal et al. teach away from stimulating the vagus nerve as per col. 1, lines 48-51, this is not understood since Marchal et al. explicitly state that their invention is designed to stimulate the vagus nerve (see for example col. 5, lines 1-10). An act that may be described as difficult to do, is clearly not a teaching away from performance of the act when Marchal et al. themselves disclose vagal stimulation.

Regarding the rejection of claims 34, 35, 37 and 38 as being unpatentable over Marchal et al. in view of Bertolucci, the applicants argue that Marchal et al. provide a specific discussion of the types of nausea and vomiting that can be treated by pancreas stimulation –namely those resulting from an osmotic imbalance-– and refers to col. 6, line 29 to col. 12, line 12. It is argued that given the specific osmotic imbalance underlying the nausea and vomiting of pregnancy, it is not common sense that nausea and vomiting caused by chemotherapy and motion sickness could also be treated by the Marchal et al. invention.

In response, the examiner argues that while Marchal et al. refers to morning sickness of pregnant women, the invention is clearly not limited to such limited operation. Marchal et al. also refer to the invention applying to athletes who experience nausea and vomiting after intensive exercise. It is suggested that nausea and vomiting can be caused by osmotic imbalances brought about by physical stress, listing exercise and pregnancy as two examples (col. 6, lines 39-67). Common sense would indicate that situations involving significant physical stress would likely bring about osmotic imbalances. Certainly people subject to chemotherapy and motion sickness would be under very stressful conditions. It would therefore be reasonable for one of ordinary skill in the art to expect the method to apply to stressful situations like chemotherapy and motion sickness. Bertolucci was not applied for its showing of stimulation location, but for its suggestion that chemotherapy and motion sickness may be treated by nerve stimulation. Given the suggestion that said conditions can be treated with nerve stimulation and the teachings of Marchal et al. that disclose that vagus nerve stimulation in particular may be effective in treating nausea and vomiting brought on by stressful situations, those of ordinary skill in the art would have considered application of the Marchal et al. invention to the treatment of motion sickness and chemotherapy as obvious.

The examiner also argues in addition to that presented above, that field-of-use limitations in the preamble of claims 34 and 37 are insufficient to saliently distinguish over the method of Marchal et al. lacking their ability to breathe life and meaning into the claim.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/
Primary Examiner, Art Unit 3766

KJS
March 28, 2011